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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,501	04/16/2001	Tyler B. Parr		5399

7590 03/27/2002

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EXAMINER
JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
1615	2

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/835,501	Applicant(s) PARR, TYLER B.	
	Examin r Robert M. Joynes	Art Unit 1615	

-- Th MAILING DATE of this communication appears on the cov r sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 4-10 recite a composition including component 1 and component 2. Applicant has not defined what component 1 and component 2 are in Claims 1 and 4-10. It is unclear what the components are therefore Claims 1 and 4-10 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 recite the respective phrases "said component 1" and "said component 2." These claims are treated as independent claims. There is no dependency upon Claim 1. Therefore, there is insufficient antecedent basis for this limitation in the claim. It is suggested that applicant amend the claims to depend upon Claim 1 to overcome this rejection.

Claims 2 and 3 further recite "and derivatives thereof." It is unclear what derivatives the applicant is trying to convey. An unlimited number of derivatives could likely be prepared from the members of the Markush groups of these claims. It is unclear what derivatives applicant is trying to include as members of the group.

Claim 4 are unclear because both claims are in improper Markush format because the term "comprising" is used. It is improper to use the term "comprising" instead of "consisting of." *Ex Parte Dotter*, 12 USPQ 382 (Bd. App. 1931) MPEP 2173.05(h). The proper Markush format is the expression "selected from the group *consisting of*" and the use of the terms "and" OR "or" only before the last Markush member. It is suggested that applicant amend the claims by replacing the words "comprising" (used twice in the claim) with the words " consisting of" in Claim 4.

Claim 8 recites that components 1 and 2 should be administered I hour before large pulsatile estrogen release of premenopausal women. It unclear what applicant is trying to convey when reciting this limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Gardiner (US 5817329). Gardiner teaches a dietary supplements comprising acetyl-L-carnitine and L-leucine, L-valine, L-mrthionine, L-arginine and ornithine (Col. 6-10, Claims 1-18). The dietary supplement is to be used by bodybuilders and athletes (Col. 4, lines 39-51). The acetyl-L-carnitine is present in the dietary supplement from about

500 mg to about 1500 mg (Col. 6, Claim 1). The additional amino acids that are included are present from about 400 mg to about 600 mg (Col. 8, Claim 11).

Claims 1-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Braswell et al. (US 5911992, hereinafter "Braswell"). Braswell teaches a composition used to treat weight gain and facilitate weight loss comprising acetyl-L-carnitine present in an amount of 100 to 1000 mg (Col. 6-8, Claims 1, 6 and 9). The composition further comprises L-phenylalanine or L-tyrosine (Col. 8, Claim 13).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardiner or Braswell. The teachings of both are discussed above. Neither reference teaches the exact concentration ranges of components 1 and 2.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amount of components 1 and 2 in the dietary supplement

One of ordinary skill in the art would have been motivated to do this to prepare various dosage levels for the different types of subjects ingesting the supplement, i.e., once daily dosages as opposed to multiple dosages or differing dosages for different conditions treated.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Monday through Friday 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER